



Michael D. Maves, MD, MBA, Executive Vice President, CEO

September 21, 2010

Attention: RIN 1210—AB45
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Room N-5653
200 Constitution Avenue, NW
Washington, DC 20210

Attention: OCIO-9993-IFC
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Attention: REG-125592-10
CC:PA:LPD:PR (REG-125592-10)
Internal Revenue Service
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Re: Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act

Dear Sir/Madam:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments regarding the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act (IFR). While overall we strongly support provisions of the IFR that are consistent with congressional intent and place patients and consumers first, we have both specific and general concerns and recommendations.

In general, physicians are often called upon to serve as advocates for their patients and represent the first and last line of defense against arbitrary and inappropriate insurer denials of medically necessary care, treatment, and services. Given the increasing complexity of the health care system, patients, particularly those who appeal (via the internal and external processes), are often vulnerable and medically fragile. Even with the support and assistance of their physician(s), the processes for challenging an insurer determination are daunting and requires physical, financial, and emotional reserves. We urge policymakers to strive for simplicity and policies that even the playing field between insurers and the insured. We believe, for the most part, the IFR moves in the right direction by ensuring that the notice and review processes are transparent and unbiased.

Clinical Integrity of Medical Decision-Making

The AMA urges the Departments to modify the IFR language and include explicit new language that ensures that the clinical integrity of medical decision-making is protected as part of the appeals process. No amount of notice or process will result in an appropriate clinical outcome if the underlying standards are not clinically appropriate, or the reviewers are not qualified to make decisions concerning the clinical issues at stake.

The AMA has adopted a Health Insurer Code of Conduct, governing both clinical and business operations of health plans, which the medical profession has found to be critical to the delivery of efficient, patient-centered health care. These principles put the patient's best interests first. Of the Code of Conduct's 10 clear principles, two of the principles directly address the need to protect the clinical integrity of medical decision-making. The relevant principles provide:

Medical Necessity

- Medical care is “necessary” when a prudent physician would provide it to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.
- All emergency screening and treatment services (as defined by the prudent layperson standard) provided by physicians and hospitals to patients must be covered without regard to prior authorization or the treating physician's or other health care provider's contractual relationship with the payer.
- Health insurers must not use financial incentives that discourage the rendering, recommending, prescribing of, or referral for medically-necessary care.
- No care may be denied on the grounds it is not “medically necessary” except by a physician qualified by education, training and expertise to evaluate the specific clinical issues.

- Patients and their physicians must have the right to a transparent appeal process and obtain a free, timely, external review of any adverse benefit decision based on “medical necessity” or a claim the service is “investigational” or “experimental.”

Benefit Management

- Clear information on benefit restrictions must be readily available to patients and physicians.
- Decisions based on formularies or other benefit management tools must be consistent with clinically appropriate medical guidelines, and physicians must have a simple, fast way to get exceptions when warranted by their patients’ medical needs.
- Adverse changes to formularies or other benefits must not be made during the plan coverage year, and physicians who have stabilized a patient on a particular medication or other treatment regime must not be forced to change those medications or other treatments, nor should these patients be required to incur additional costs based upon such changes.
- Financial incentives must not corrupt benefit decisions, and all financial incentives potentially impacting benefit decisions must be fully disclosed.

The notice requirements and many other provisions of the internal and external appeals process proposed in the IFR go a long way toward achieving many of the above process criteria. As a result, we strongly support these patient and consumer protections embodied by the IFR.

Nevertheless, the IFR does not contain the necessary safeguards to ensure that the tests used by insurers to determine whether a treatment is “medically necessary” or “experimental or investigational” are clinically appropriate, or that the individuals who are applying those tests are clinically qualified. To the contrary, the IFR contains proposed regulatory language that will gut the strong protections contained in the proposed framework unless modified and amended. Specifically, on page 43356, under (c)(iii)(2)(i), the IFR provides that:

[t]he State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations that are **based on the issuer’s (or plan’s) requirements** for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(Emphasis added.) To the extent that an insurer/plan does not require definitions that are appropriate, no amount of notice or process will result in an appropriate clinical outcome. At the state level, this phenomenon has been addressed through the adoption of baseline definitions and rules that protect the clinical integrity of medical decision-making. **We strongly urge the Departments to adopt the same or similar mandatory definitions and rules below as part of the required elements of state and federal processes:**

- Definition of “clinical criteria and utilization review protocols.” “Clinical criteria and utilization review protocols” means the written policies, written screening procedures, drug formularies or lists of covered drugs, decision rules, decision abstracts, clinical protocols, practice guidelines, medical protocols used by the Insurer/Plan to determine the necessity and appropriateness of health care services.
- Basis of clinical criteria. “Clinical criteria and utilization review protocols” must: be based on nationally-recognized standards; be developed in accordance with the current standards of national accreditation entities; reflect community standards of care; ensure quality of care and access to needed health care services. Clinical criteria must, if practicable, be evidence-based. Clinical criteria and utilization review protocols must be sufficiently flexible to allow deviations from norms when justified on case-by-case bases.
- Lack of evidence-based standards. If no independently-developed evidence-based standards exist for a particular treatment, testing, or imaging procedures, Insurer/Plan will not deny coverage of the treatment, testing, or imaging procedures based solely on the grounds that the treatment, testing, or imaging does not meet an evidence-based standard.
- Basis of utilization review determinations. All utilization review determinations made by the Insurer/Plan must be based on written clinical criteria.
- Physician role in clinical criteria development. Prior to establishing, or substantially or materially altering, clinical criteria and review protocols, Insurer/Plan will obtain input from actively practicing physicians within the Insurer/Plan’s provider network and within the Insurer/Plan’s service area. Such physicians must represent major areas of specialty and be certified by the boards of the various American medical specialties. The Insurer/Plan will seek input from physicians who are not employees of the Insurer/Plan, or consultants to the Insurer/Plan if the physician is a consultant only for the purpose of developing clinical criteria and utilization review protocols.
- Obligation to update. Insurer/Plan will periodically review and update its clinical criteria and protocols and maintain evidence of such periodic reviews. Clinical criteria and utilization review protocols must be updated at least biennially and as new treatments, applications, and technologies.

The foregoing definitions and rules are essential to medical decision-making that is grounded in clinical integrity as opposed to considerations such as costs, profits, and administrative convenience.

INTERNAL CLAIMS AND APPEALS

With respect to internal claims and appeals processes for **individual health insurance coverage**, we support the IFR provision mandating that all of the **group health coverage requirements** discussed below will apply to the internal claims and appeals process for individual health

coverage. We also support the additional three requirements that protect consumers in the individual market, including: (1) expanding the appeals process to cover initial eligibility determination; (2) abolishing any second-level review; and (3) the specific documentation requirements.

As noted in the IFR, the internal claims and appeals processes for **group health coverage** (plans and issuers) must initially incorporate the internal claims and appeals processes set forth in 29 CFR 2560.503–1 and update such processes in accordance with standards established by the Secretary of the U.S. Department of Labor (DOL).

We applaud and strongly support the additional six supplemental IFR requirements, including those that:

- expand the definition of adverse benefit determination(s) to include, among other things, rescission of coverage;
- shorten the period of benefit determination notification from 72 hours to 24 hours;
- require insurers and plans to provide, free of charge, any new or additional evidence considered, relied upon or generated in advance of a notification of determination;
- ensure the impartiality of the persons involved in decision-making including a bar on bonuses based on denials; and
- mandate the provision of culturally and linguistically appropriate notice(s) that include the relevant information needed to understand what claim(s) have been denied and the basis of the denial in addition to the recourse available to the insured.

We also strongly support the proposal to issue a model notice that would satisfy all of the requirements under this IFR. While the actual content of the notices is important, **equally important is the organization of the notice, the use of font and other formatting techniques, as well as issues related to comprehension.** Physicians and their staff often must read these notices and to the extent there is uniformity, it will decrease time expended to find the relevant information and reduce confusion.

Finally, we would welcome the opportunity to work on a Health Insurance Portability and Accountability Act standard for an electronic appeals process, as we believe there is a tremendous opportunity for streamlining appeals through such a standard.

EXTERNAL REVIEW

With respect to external review, the law establishes a process for determining whether a State external review process or a Federal external review process applies. While we are, generally, greatly encouraged and pleased by the IFR provisions concerning external reviews, we strongly recommend the addition of several elements that are minimally necessary to protect consumers.

In addition, we recommend modification of proposed language and the inclusion of definitions and baseline rules that protect the integrity of clinical decision-making.

Conflicts of Interests

We strongly support the elements identified as the minimum consumer protections that must be a part of a State external review process that were drawn from the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners (NAIC Model Act). In particular, we applaud those elements that prohibit insurers from having a role in the selection or payment of Independent Review Organizations (IRO). We support the additional elements that ensure the IROs do not have a conflict of interest and remain independent and viable (even where they make determinations adverse to insurers).

Evidence-Based Standards and Best Evidence

We strongly urge the Departments to clarify and expand upon the appropriate use of evidence-based standards for the State and Federal appeals process, as well as the definition of best evidence. The following suggested changes should be added as elements that represent essential consumer protections. We are extremely concerned that the omission of these clarifying elements will seriously undermine the ability of physicians to provide patient-centered care that reflects medical necessity and quality care. The AMA has vigorously supported efforts to increase the evidence base of medicine and has been a vocal advocate of comparative clinical effectiveness research, for example. While we are very aware that evidence-based medicine, when properly translated and applied to practice, has the potential to enhance care, we are equally and acutely aware that the evidence-based standards can be misused or developed without the requisite emphasis on clinical considerations or without proper consideration of variations within communities and among individuals. In short, without proper precaution, standards could be fashioned to represent “evidence-based medicine,” but may in practice be highly detrimental to certain individual patients or categories of patients. As a result, we strongly urge the addition of the following new elements.

We recommend that the Departments include an element that requires that the review of adverse determinations of medical necessity will be based on whether the case involved health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease or its symptoms in a manner that is:

- (a) in accordance with generally-accepted standards of medical practice;
- (b) clinically appropriate in terms of type, frequency, extent, site and duration; and,
- (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

We urge adoption of additional language that provides further that “generally-accepted standards of medical practice” means “standards that are based on credible scientific evidence published in peer-reviewed medical literature generally-recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in the relevant clinical areas and any other relevant factors.” This is essentially the definition of “medical necessity,” which is incorporated in the AMA’s Health Insurer Code of Conduct, and was adopted in multi-district litigation settlements with some of the largest health plans in the country. Inflexibly limiting reviews to “evidence-based standards” without accounting for the factors above undermines the delivery of patient-centered care (and could actually exacerbate health disparities). Furthermore, the rigid application of “evidence-based” standards is questionable when the “evidence” on which they are based consists primarily of actuarial assumptions rather than medically-based standards of care.

We also urge the Departments to include an element that clarifies that the best evidence used in the appeals process afford appropriate weight and deference to expert opinion, including that of the treating physician. To do otherwise could open the door to conferring disproportionate weight on insufficiently qualified non-physician individuals who do not have all the relevant information and have not examined the patient.

It is also essential that the clinical integrity of the medical decision-making process be protected throughout internal and external appeals. To ensure that the integrity of these decisions is ensured, the definitions of “medical necessity,” “experimental,” and “investigational” must be medically appropriate.

Moreover, the individuals who make utilization review decisions must be clinically qualified to do so by professional education, training, licensure, and experience specific to the medical issue in question. One way to ensure that the IRO reviewers focus on the patient's best interest would be to mandate the questions that they must answer along the following lines:

The expert reviewers shall be instructed by the IRO to answer the three questions listed below. No other questions shall be posed to the expert reviewers.

- a) Is the requested therapy likely to be more beneficial for the enrollee than that authorized by the plan? List the reasons that the therapy should or should not be provided by the plan, citing the enrollee’s specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence;
- b) Are the medical records and accompanying information sufficient to answer the question noted above? If not, please notify <NAME OF IRO> immediately of the additional information required; and
- c) Is there any other treatment not under consideration that can reasonably be expected to be more beneficial for the patient?

This would ensure that the patient's welfare is the focus of the inquiry, and only the medically-relevant issues to the patient's welfare are considered.

Application of Federal Process v. State Process

The AMA supports application of the federal external review process to all plans and issuers in a state only if: (1) there does not exist an applicable state external review process that meets the prescribed requirements and elements laid out in the IFR (as modified by our recommended changes) or (2) the state external review process does not apply to all issuers/plans and the consumer protections are not as stringent as those laid out in federal law. We generally would not support superseding state laws that provide a higher level of consumer protection even though the standards/requirements among insurers/plans would vary.

Nationally-Accredited Entities

While we support mechanisms such as accreditation that would ensure the quality and independence of IRO services, we do not support the uncertainty created by not defining which national private accrediting entities will be recognized as IRO accreditors.

We also strongly urge the inclusion of another element that provides that the treatment decisions or recommendations by physicians must be reviewed only by IRO experts who are actively practicing physicians familiar with the medical condition or treatment in question, of the same specialty, and licensed and actively practicing in the same state where the treating physician is practicing. If out-of-state review entities contract with physician reviewers who are not practicing within the same state as the treating physician, it will weaken the use of relevant, case-specific information by equivalently qualified peer physicians. Furthermore, the Departments should require that any changes in the standards for IRO accreditation by the accrediting entity, must be reviewed and approved by the relevant state insurance commissioners or NAIC where they are authorized to confer accreditation.

NOTICES

We strongly support the IFR setting forth the form and manner of providing **notices** in connection with internal claims and appeals and external review processes. The complexity of the appeals and external review process is a significant barrier for many patients and consumers. This is all the more true when there are language barriers. The notice provisions will ensure that patients/consumers will receive notice and understand the nature of their rights and deadlines.

CONCLUSION

We appreciate the opportunity to provide comments and look forward to working with the agencies to protect consumers and patients access to medically-necessary care. It is essential that

U.S. Department of Labor
Department of Health and Human Services
Internal Revenue Service
September 21, 2010
Page 9

the appeals process is simplified, streamlined, and evens the playing field between consumers/patients and insurers.

Sincerely,

A handwritten signature in black ink that reads "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA